## **REMARKS**:

Applicants have amended claims 1, 3, 4, 10, and 12, cancelled claims 6-9, 11 and 13-16 without prejudice, and added new claim 17. Claims 1, 3, 4, 10, 12 and 17 are pending in the application. Applicants respectfully request reconsideration of the application, as amended, and respectfully submit that the application is in condition for allowance.

# I. APPLICANT'S AMENDMENT DOES NOT PRESENT NEW MATTER UNDER 35 U.S.C. 132.

In page 2 of the Office action, the Examiner asserts that the limitation directed to "between about 0.2mm and about 30mm" is new matter. Applicants respectfully disagree with this assertion on the basis that the specification recites in part "the diameter of the helix, D (Figure 3), formed by the windings will normally be in the range of about 0.2mm to about 30mm." (p. 3, lines 19-20). Accordingly, the cited claim limitation is not new matter and, therefore, has not been canceled.

## II. REJECTION UNDER 35 U.S.C. 102(e).

## A. The Office Action Rejection.

In pages 2-5 of the Office action, claims 1, 3-4, 6-10, and 12-15 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,531,788 to Dibie et al. ("Dibie"). Since claims 6-9, 11 and 13-16 were cancelled without prejudice, only the rejection of independent claims 1 and 4 and dependent claims 3, 10 and 12 is addressed. The Applicants respectfully traverse the rejection, however, to expedite prosecution of the application, Applicants offer the above amendments and the following remarks.

## B. Claims 1, 3, 4, 10, 12 and 17 Are Not Anticipated by Dibie.

The Dibie patent describes a filter. The filter prevents a clot from migrating to the right heart from veins of other parts of the body. More specifically, the filter is made of a resilient, spiral-shaped wire having three non-touching turns. A middle turn has a diameter that is greater than the diameter of the other two turns. (col. 6, lines 44-47). The Dibie patent explains that the turn of diameter d3 is always greater in diameter than the vena cava to obtain the best flattening effect by the filter. (col. 7, lines 11-14). The Dibie patent further explains that a distal or second end of the wire is in the form of a radio-opaque cylinder. The cylinder 6 is free and smooth and rounded to avoid damaging the wall of the vena cava once it is in place. (col. 7, lines 39-45). The radio-opaque cylinder materials allows insertion of the filter to be monitored with X-rays. (col. 3, lines 1-6; col. 5, lines 64-65). Thus, the Dibie patent merely discloses a stiff wire that is biased to wind into non-touching turns to provide a filter having a radio-opaque cylinder at one end and that may be mounted within a vena cava. The Dibie patent, however, fails to disclose or suggest a number of aspects of Applicant's claims.

First, the Dibie patent does not disclose or suggest a vasooclusion device, much less a soft, flexible vasooclusion coil, that occludes a vessel or a cavity. To the contrary, the Dibie patent describes a filter and, more specifically, a resilient filter that physically expands a vessel or vein. (See, e.g., Figs., 5-6).

Second, the Dibie patent does not disclose or suggest a proximal end having a coupling member formed therein to detachably couple the proximal end of the coil to a distal end of a wire.

Rather, the Dibie patent explains that the distal second end is in the form of a radio-paque cylinder that is smooth and rounded. (col. 7, lines 39-45).

Third, the Dibie patent does not disclose or suggest a helical coil that is wound into a multiplicity of windings, as claimed. As discussed in the specification of the subject application, a coil may include windings having a diameter of about 0.01 mm to about 0.50 mm that are wound into a helix having a diameter between about 2.0 to 30 mm. Instead of such a "coil of a coil" structure, the Dibie patent merely discloses a wire that is wound into non-touching windings.

Fourth, with respect to dependent claims 12 and 17, the Dibie patent does not disclose or suggest a multiplicity of windings having a first diameter between the proximal and distal ends, the first diameter being between about 0.2 mm and about 30 mm. Rather, the cited patent makes no reference to these diameters. Instead, the Digbie patent merely refers to diameters of 27mm, 31.5mm and 36mm (col. 7, lines 13-18), the diameter d3 being at least 1.25 or 1.42 times as large as diameters d2 and d4, and the diameter d3 being more than 2.5 times the axial extent 3p of the filter at rest. (col. 6, line 51 – col. 7, line 5).

Thus, the Applicants respectfully submit that independent claims 1 and 4 are not anticipated by the Dibie patent and are allowable. Further, the Applicants respectfully submit that dependent claims 3, 10, 12 and 17, which depend from respective independent claims 1 and 4, are also allowable since these dependent claims recite further novel and nonobvious limitations and incorporate all of the limitations of their respective independent claims.

## III. REJECTIONS UNDER 35 U.S.C. 103(a).

#### A. The Office Action Rejections.

In pages 3-5 of the Office action, claims 1, 3-4, 6-10, and 12-15 were rejected under 35 U.S.C. §103(a) as being obvious over the Dibie patent.

In pages 5-6 of the Office action, claims 6, 11, 13 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,649,949 to Wallace *et al.* ("Wallace"). Rejected claims 6, 11, 13, and 16 were canceled without prejudice. Accordingly, the rejection over the Wallace patent is moot, and the Applicants respectfully request that the rejection be withdrawn.

Thus, only the rejection of claims 1, 3, 4, 10, and 12 over the Dibie patent is addressed. The Applicants respectfully traverse the rejection over the Dibie patent, however, to expedite prosecution of the application, the Applicants offer the above amendments and the following remarks.

## B. Claims 1, 3, 4, 10, 12, and 17 Are Patentable Over Dibie.

To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. MPEP §2143.03. The Dibie patent, as previously discussed, has a number of deficiencies relative to the Applicants' claims.

Further, a person of ordinary skill in the art would not be motivated to modify or transform the filter described in the Dibie patent into a vaso-occlusion coil as claimed. The filter described in the Dibie patent is utilized for a fundamentally different purpose than the vasooclusion coil of the subject application. Transforming the filter described in the Dibie patent into a vasooclusion coil as claimed would, by definition, remove the "filtering" function from the filter.

Moreover, it would be undesirable to occlude the vena cava, which would prevent blood from returning to the heart, and risk substantial injury to a patient receiving the device described in the Dibie patent. Further, it would be undesirable to use a rigid device, such as the filter described in the Dibie patent, as a vasoocclusion coil because it would risk rupturing a weakened vessel wall, such as an aneurysm.

The Dibie patent also teaches away from a proximal end having a coupling member formed therein to detachably couple the proximal end to the distal end of the wire. As previously discussed, the Dibie patent describes a proximal end in the form of a radio-paque cylinder that is smooth and rounded and includes radio-opaque tracking materials. Transforming the radio-opaque cylinder into a coupling member or a coupling member formed within the proximal end would negate or inhibit the radio-opaque tracking and remove the "smooth" and "rounded" features of the cylinder, which ensure that the vena cava is not damaged. (col. 5, lines 64-65; col. 7, lines 39-45; col. 9, lines 6-9).

Thus, the Applicants respectfully submit that independent claims 1 and 4 are patentable over the Dibie patent and are allowable. Further, the Applicants respectfully submit that dependent claims 3, 10, 12 and 17, which depend from respective independent claims 1 and 4, are also allowable since these dependent claims recite further novel and nonobvious limitations and incorporate all of the limitations of their respective independent claims.

7013072001 PATENT

## IV. CONCLUSION.

Based on the forgoing amendments and remarks, Applicants respectfully submit that pending claims 1, 3, 4, 10, 12 and 17 are allowable over the cited references. A timely Notice of Allowance is respectfully requested.

Date: August 7, 2003

Respectfully submitted,

**BINGHAM MCCUTCHEN, LLP** 

By

Gary D. Lueck Reg. No. 50,791

Attorney for Applicants

Three Embarcadero Center, Suite 1800

San Francisco, California 94111

Telephone: (213) 680-6400 Facsimile: (213) 680-6499